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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,027	11/14/2003	Romano Mongiorgi	2503-1074	7509

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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,027

Applicant(s)

MONGIORGI, ROMANO

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed April 6, 2004 fails to fully comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. In the present case, the information disclosure statement fails to full comply with 37 CFR 1.98(a)(1) because no copy of either of the references of Gortner et al. (UU1) or McCay et al. (WW1) accompanied the information disclosure statement as indicated by Applicant. Therefore, the Examiner has not considered the references, unless indicated else wise. Applicant is required to submit a copy of the cited references.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 1 are rendered under certain by the phrase "Compositions for stomatological use containing as active ingredients compounds of rhubarb (*Rheum* genus) and *Spinacia oleracea* L." because it is uncertain as to whether the instantly claimed composition comprises active compounds from only rhubarb or compounds from both rhubarb and *Spinacia oleracea* L.. The lack of clarity renders the claim vague and indefinite.

Claims 2-4 recite the limitation "wherein the plant compounds" in lines 1-2. There is a lack of clear antecedent basis for this limitation in the claims.

Claim 6 provides for the use of rhubarb (*Rheum* genus) and *Spinacia oleracea* L. compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 6 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Fedorov et al. (OO1, SU 615931).

Applicant claims compositions for stomatological use containing as active ingredients compounds of rhubarb (*Rheum* genus) and *Spinacia oleracea* L., either alone or in association with one another, mixed with suitable excipients. Applicant further claims compositions as claimed in claim 1, in the form of paste, gel, mouthwash, spray solution, sweets, chewing gum, solution or powder. Applicant further claims compositions as claimed in claim 1, wherein the plant compounds are in the form of liquid, soft or dry extracts. Applicant further claims compositions as claimed in claim 1, wherein the plant compounds are obtained by hydroalcoholic extraction from *Spinacia oleracea* L. leaves. Applicant further claims compositions as claimed in claim 2 in the form of paste, gel, mouthwash, spray solution, sweets, chewing gum, solution or powder. Applicant further claims compositions as claimed in claim 4 in the form of paste, gel, mouthwash, spray solution, sweets, chewing gum, solution or powder.

Fedorov teaches toothpaste having improved prophylactic activity against periodontitis comprising spinach (*Spinacia oleracea* L.) extract mixed with suitable excipients.

The reference anticipates the claimed subject matter.

Claims 1-3 are 5, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hikada et al. (VV1), Ai (NN1, CN 1115248 A), and Nanba et al. (O).

Applicant's claimed invention of Claims 1, 2 and 5 was set forth above. Applicant further claims the compositions as claimed in claim 1, wherein the plant compounds are obtained by hydroalcoholic extraction from rhubarb roots. Applicant further claims compositions as claimed in claims 3 and 4 in the form of paste, gel, mouthwash, spray solution, sweets, chewing gum, solution or powder.

Hikada teaches a composition comprising an acetone/water/ethanol extract of rhubarb root (*Rhei rhizoma*) in the form of a solution and containing a polyphenolic compound (fraction IV), which contains useful substances for the prevention or oral calcium phosphate precipitation (calculus formation) that contributes to the progression of gingivitis or periodontal diseases.

Ai teaches a Chinese-medicinal tincture for treating toothache prepared by mixing and crushing 11 Chinese-medicinal components such as coptis root, rhubarb, Fructus piperis longi, cimicifuga rhizome and gypsum, filtering and adding menthol and alcohol.

Nanba teaches a plaque formation inhibitor comprising a hydroalcoholic (water/methanol) extract of rhubarb. The plant extract can be used alone or as an extract mixture with other disclosed plant inhibitors, as well as with other agents or

drugs. Furthermore, the preparation may be used directly in an oral cavity or mixed with toothpaste.

The references anticipate the claimed subject matter.

Claims 1, 2, 5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Shibuya et al. (N) and Inahata et al. (P).

Applicant's claimed invention was set forth above.

Shibuya teaches a composition periodontosis comprising an extract of rhubarb root for oral application that suppresses the formation of sordes on tooth and tooth caries. The Shibuya' composition is in the form of a toothpaste, mouthwash, troche and chewing gum.

Inahata teaches a deodorant for use in food, such as candies and gums, dentrifies and mouth cleaners in the form of a solution, paste, powder or block, comprising a compound, *i.e.*, at least one component selected from vitamins K1, K2 and K3, which are extracted from spinach.

The references anticipate the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fedorov et al. (OO1, SU 615931) in view of Hikada et al. (VV1), Ai (NN1, CN 1115248 A) and Nanba et al. (O).

Fedorov teaches toothpaste having improved prophylactic activity against periodontitis comprising spinach (*Spinacia oleracea* L.) extract mixed with suitable excipients.

The teachings of Fedorov are set forth above. Fedorov teaches the claimed composition except for rhubarb. However, it would have been obvious to one of ordinary skill in the art to add the instantly claimed ingredient to provide the instantly claimed invention because at the time the invention was made it was known in the art that the addition of rhubarb to compositions for stomatological use was beneficial, as evidenced by the teachings of Hikada, Ai and Nanba. At the time the invention was made, one of ordinary skill would have been motivated and one would have had a reasonable expectation of success to add an extract of rhubarb to the spinach extract taught by Fedorov to provide the instantly claimed compositions because Hikada teaches a composition comprising an acetone/water/ethanol extract of rhubarb root (*Rhei rhizoma*) in the form of a solution and containing a polyphenolic compound (fraction IV) and suggests the usefulness of the substance for the prevention of oral calcium phosphate precipitation (calculus formation) that contributes to the progression of gingivitis or periodontal diseases; Ai teaches a tincture preparation for treating toothache comprising rhubarb; and, Nanba teaches a plaque formation inhibitor comprising a hydroalcoholic (water/methanol) extract of rhubarb, wherein the

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preparation may be used directly in an oral cavity or mixed with toothpaste. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add any of the claimed ingredients in the making of the claimed methods because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-5 and 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gortner et al. (UU1), and in further view of McCay et al. (WW1) and Kasidas et al. (U).

Applicant's claimed invention was set forth above.

Gortner teaches compositions comprising oxalate (e.g., oxalate and orange juice and oxalate and food), which when administered to rats produced a hard deposit that grossly resembled human dental calculus on the teeth of rats. Gortner further teaches, "Natural oxalate-containing foods, such as spinach and rhubarb produced the characteristic protective films on the molars of rats within 1 week."

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The teachings of Gortner are set forth above. It is not clear from the teachings of Gortner whether rhubarb and spinach were in combination to provide the beneficial, disclosed functional effect. However, it would have been obvious to one of ordinary skill in the art to provide the instantly claimed composition for stomatological use containing as active ingredients compounds obtained from both rhubarb and *Spinacia oleracea* L. to provide the instantly claimed invention because at the time the invention was known it was known in the art that oxalate was present in rhubarb and spinach, as evidenced by the teachings of McCay and Kasidas. At the time the invention was made, one of ordinary skill in the art would have been motivated and would have had a reasonable expectation of success to add the instantly ingredients to provide the claimed compositions because Gortner teaches, "The presence of oxalic acid or its Na salt in the rats food or drink prevented or diminished the decalcification of teeth which accompanies the ingestion of phosphoric and citric acid solutions"; McCay teaches that sodium oxalate ingested with food deposits patches on the teeth and that the prevention of molar teeth by acid beverages can be effected by the administration of oxalic acid dissolved in an acid beverage, such as rhubarb juice combined with equal parts of lemon juice; and Kasidas teaches that spinach and rhubarb comprise high levels of oxalate. Thus, the claimed invention is no more than the combining of active ingredients known in the art to exert stomatological activity, wherein the active ingredients are compounds, namely oxalate compounds and wherein the oxalate compounds were known to be extracted from the claim-designated plants of rhubarb (genus *Rheum*) and spinach (*Spinacia oleracea* L.).

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Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHELE FLOOD
PATENT EXAMINER

MCF
November 29, 2004